

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application of: Markland and Ladner  
Serial No.: 08/676,125  
Filed: September 25, 1996  
Entitled: Kallikrein-Inhibiting "Kunitz  
Domain" Proteins and Analogues  
Thereof

Art Unit: 1805

Examiner: N. Degen

Attorney Docket No.: DYX-006.2P US(Markland-1B)

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Assistant Commissioner for Patents  
Washington, D.C. 20231

### INFORMATION DISCLOSURE STATEMENT

UNDER 37 CFR §§ 1.56, 1.97 AND 1.98

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Sir:

In accordance with the duty of disclosure under 37 CFR § 1.56, Applicants submit this Information Disclosure Statement pursuant to 37 CFR §§ 1.97 and 1.98 in the above-identified application for consideration by the Patent Office. Copies of the cited documents are enclosed for the Examiner's convenience. The documents cited are also listed on the accompanying Form PTO-1449.

Because this Statement is being submitted before a Final Office Action, the appropriate fee is enclosed, pursuant to 37 CFR § 1.97(c)(1) and § 1.17(p). {check no. 1129}

### U.S. PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	NAME	FILING DATE IF APPROPRIATE
AA	US 4,330,440	05/18/82	Ayers, et al.	
AB	US 4,609,725	09/02/86	Brady, et al.	

100	<b>AC</b>	US 4,179,337	12/18/79	Davis et al.	
100	<b>AD</b>	US 4,195,128	03/25/80	Hildebrand, et al.	
100	<b>AE</b>	US 4,247,642	01/27/81	Hirohara, et al.	
100	<b>AF</b>	US 4,229,537	10/21/80	Hodgins, et al.	
100	<b>AG</b>	US 3,969,287	07/13/76	Jaworek, et al.	
100	<b>AH</b>	US 5,223,409	06/29/93	Ladner, et al.	
100	<b>AI</b>	US 3,691,016	09/12/72	Patel	
100	<b>AJ</b>	US 4,153,687	05/08/79	Schnabel, et al.	
100	<b>AK</b>	US 4,118,481	10/03/78	Schnabel, et al.	

#### FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	NAME
100	<b>AL</b>	WO-A-93 14122	07/22/93	(Novo Nordisk AS)
100	<b>A M</b>	WO-A-93 14121	07/22/93	(Novo Nordisk AS)
100	<b>AN</b>	WO-A-93 14120	07/22/93	(Novo Nordisk AS)
100	<b>AO</b>	EP 0 285 123 A2	10/05/88	(Suomen Sokeri Oy)
#	<b>AP</b>			

#### OTHER ART

100	<b>AQ</b>	Adelman et al., Blood, 68(6):1280-1284 (1986)
100	<b>AR</b>	Albrecht et al., Hoppe-Seyler's Z Physiol. Chem., 364:1697-1702 (1983)
100	<b>AS</b>	Albrecht et al., Hoppe-Seyler's Z Physiol Chem., 364:1703-1708 (1983)
100	<b>AT</b>	Anba et al., Biochimie, 70(6):727-733 (1988)
100	<b>AU</b>	Angliker et al., Biochem. J., 241(3):871-875 (1987)
100	<b>AV</b>	Atherton et al., J. Chem. Soc. Perkin Trans., 1:538-546 (1981)
100	<b>AW</b>	Auerswald et al., Bio. Chem. Hoppe-Seyler, 369(Suppl):27-35 (1988)
	<b>AX</b>	Balduyck et al., Biol. Chem. Hoppe-Seyler, 366:9-14 (1985)
	<b>AY</b>	Baneyx & Georgiou, J. Bacteriol., 173(8):2696-2703 (1991)
	<b>AZ</b>	Baneyx and Georgiou, J. Bacteriol., 172(1):491-494 (1990)
	<b>BA</b>	Berndt et al., Biochemistry, 32(17):4564-4570 (1993)
	<b>BB</b>	Bhoola et al., Pharmacological Reviews, 44(1):1-80 (1992)
	<b>BC</b>	Browne et al., GeneBank, Accession No. M74220 (1991)
	<b>BD</b>	Broze et al., Biochemistry, 29(33):7539-7546 (1990)
	<b>BE</b>	Brus et al., Pediatr. Res., 41(1):120-127 (1997)
	<b>BF</b>	Budavari, ed., Merck Index, eleventh ed., ISBN 911910-28-X, entries 923,1745,2740,7425 (1989)
	<b>BG</b>	Carey and Sundberg, Advanced Organic Chemistry, Third ed., ISBN 0-306-43456-3, pp.678-686 (1990)
	<b>BH</b>	Chung et al., GenBank, Accession #125184 (1995)
	<b>BI</b>	Coleman et al., Proc. Assoc. Am. Physicians, 109(1):10-22 (1997)

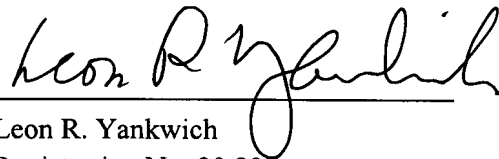
<b>BJ</b>	Colman et al., Hemostasis and Thrombosis, Second Edition (Colman et al., eds; ISBN 0-397-50679-1) Chap. 1, pp3-17 (1987)
<b>BK</b>	Cumming and Nimmo, Crit. Care Med., 20(8):1134-1139 (1992)
<b>BL</b>	Currie et al., Tetrahedron, 49(17):3489-3500 (1993)
<b>BM</b>	DeLa Cadena et al., et al., FASEB Journal, 9:446-452 (1995)
<b>BN</b>	DeLa Cadena et al., et al., Transact. Assoc. Am. Physicians, 105:229-237 (1992)
<b>BO</b>	Dennis et al., J. Biol. Chem., 270(43):25411-25417 (1995)
<b>BP</b>	Dennis and Lazarus, J. Biological Chem., 269(35):22129-22136 (1994)
<b>BQ</b>	Dennis and Lazarus, J. Biological Chem., 269(35):22137-22144 (1994)
<b>BR</b>	Diaz et al., Tetrahedron, 49(17):3533-3545 (1993)
<b>BS</b>	DiMaio et al., FEBS Lett. 282(1):47-52 (1991)
<b>BT</b>	Eigenbrot et al., Protein Engineering, 3(7):591-598 (1990)
<b>BU</b>	Ellis et al., Ann. NY Acad. Sci., 667:13-31 (1992)
<b>BV</b>	Fidler and Ellis, Cell, 79:185-188 (1994)
<b>BW</b>	Fields and Noble, Int. J. Peptide Protein Res., 35:161-214 (1990)
<b>BX</b>	Fraedrich et al., Thorac. Cardiovasc. Surg., 37(2):89-91 (1989)
<b>BY</b>	Freidinger et al., J. Org. Chem. 47(1):104-109 (1982)
<b>BZ</b>	Gardell, Toxicol. Pathol., 21(2):190-198 (1993)
<b>CA</b>	Girard et al., J. Biol. Chem., 266(8):5036-5041 (1991)
<b>CB</b>	Girard et al., Nature, 338:518-20 (1989)
<b>CC</b>	Hoover et al., Biochemistry, 32:10936-10943 (1993)
<b>CD</b>	Hortin and Trimpe, J. Biol. Chem., 266(11):6866-6871 (1991)
<b>CE</b>	Hynes et al., Biochemistry, 29:10018-10022 (1990)
<b>CF</b>	Kemp and Bowen, Tetrahedron Letts., 29(40):5077-5080. (1988)
<b>CG</b>	Kido et al., Biochem. & Biophys. Res. Comm., 167(2):716-721 (1990)
<b>CH</b>	Kido et al., J. Biol. Chem., 263(34):18104-18107 (1988)
<b>CI</b>	Kline et al., Biochem. Biophys. Res. Commun., 177(3):1049-1055 (1991)
<b>CJ</b>	Kurjan and Herkowitz, Cell, 30:933-943 (1982)
<b>CK</b>	Laskowski and Kato, Ann. Rev. Biochem., 49:593-626 (1980)
<b>CL</b>	Leatherbarrow and Salacinski, Biochemistry, 30(44):10717-10721 (1991)
<b>CM</b>	Lohmann and Marshall, Refract. Corneal. Surg. 9(4):300-302 (1993)
<b>CN</b>	Lucas et al., J. Biological Chem., 258(7):4249-4256 (1983)
<b>CO</b>	McConnell et al., J. Med. Chem. 33(1):86-93 (1990)
<b>CP</b>	MacGilchrist et al., Clin. Sci. (Colch), 87(3):329-335 (1994)
<b>CQ</b>	Mann and Lundblad, Hemostasis and Thrombosis, Second Edition (Colman et al., eds; ISBN 0-397-50679-1) Chap 10, pp148-161 (1987)
<b>CR</b>	March, Advanced Organic Chemistry, Third Edition (ISBN 0-471-88841-9) pp.396-398;1057-1060;1099-1100 (1985)
<b>CT</b>	Merrifield, Science, 232:341-347 (1986)
<b>CU</b>	Merrifield, J. Amer. Chem. Soc., 85:2149-2154 (1963)
<b>CS</b>	Miyajima et al., Gene, 37:155-161 (1985)
<b>CV</b>	Monteseirin et al., Allergol. Immunopathol. (Madr), 20(5):211-214 (1992)

<b>CW</b>	Naess et al., Eur. J. Surg., 160(2):77-86 (1994)
<b>CX</b>	Nagai et al., Tetrahedron., 49(17):3577-3592 (1993)
<b>CY</b>	Nagai and Sato, Tetrahedron Lett., 26(5):647-650 (1985)
<b>CZ</b>	Neuhaus et al., Lancet, 2(8668)924-925 (1989)
<b>DA</b>	Novotny et al., J. Biol. Chem., 264(31):18832-18837 (1989)
<b>DB</b>	Okamoto et al., Agents Actions Suppl., 38(Pt1):198-205 (1992)
<b>DC</b>	O'Reilly et al., Cell, 79:315-328 (1994)
<b>DD</b>	Park and Tulinsky, Biochemistry, 25(14):3977-3982 (1986)
<b>DE</b>	Putterman, Acta Chir. Scand., 155(6-7):367 (1989)
<b>DF</b>	Robbins, Hemostasis and Thrombosis, Second Edition (Colman et al., eds; ISBN 0-397-50679-1), Chap. 21, pp340-357 (1987)
<b>DG</b>	Scatchard, Ann. N.Y. Acad. Sci., 51:660-672 (1949)
<b>DH</b>	Schechter and Berger, Biochem. Biophys. Res. Commun. 32(5):898-902 (1968)
<b>DI</b>	Schechter and Berger, Biochem. Biophys. Res. Commun., 27(2):157-162 (1967)
<b>DJ</b>	Schmaier et al., Hemostasis and Thrombosis, Second Edition (Colman et al., eds; ISBN 0-397-50679-1), Chap.2, pp18-38 (1987)
<b>DK</b>	Schmidt et al., Swiss-Prot, Accession #124392 (1992)
<b>DL</b>	Schnabel et al., Biol. Chem. Hoppe-Seyler, 367:1167-1176 (1986)
<b>DM</b>	Sheppard and Williams, Int. J. Peptide Protein Res., 20:451-454 (1982)
<b>DN</b>	Sheridan et al., Dis. Colon Rectum, 32(6):505-508 (1989)
<b>DO</b>	Sprecher et al., PNAS USA, 91:3353-3357 (1994)
<b>DP</b>	Stadnicki et al., J. Invest. Med., 44(3):299A (1996)
<b>DQ</b>	Stadnicki et al., 10th World Cong. Gastroenterology, Poster #1166P (1994)
<b>DR</b>	Tian et al., Int. J. Peptide Protein Res., 40(2):119-126 (1992)
<b>DS</b>	Van der Logt et al., Biochemistry, 30(6):1571-1577 (1991)
<b>DT</b>	Van Dijk et al., EMBO J., 11(8):2819-2828 (1992)
<b>DU</b>	Varadi and Patthy, Biochemistry, 23(9):2108-2112 (1984)
<b>DV</b>	Varadi and Patthy, Biochemistry, 22(10):2440-2446 (1983)
<b>DW</b>	Vedvick et al., J. Ind. Microbiol., 7:197-201 (1991)
<b>DX</b>	Wade et al., Biopolymers, 25:S21-37 (1986)
<b>DY</b>	Wagner et al., Biochem Biophys. Res. Comm., 186:1138-1145 (1992)
<b>DZ</b>	Wilson et al., Tetrahedron, 49(17):3655-3663 (1993)
<b>EA</b>	Wun et al., J. Biol. Chem. 263(13):6001-6004 (1988)

Applicants do not represent that any of the documents submitted herein is material prior art to this invention or that the list represents an exhaustive search of documents related to this invention.

Applicants respectfully request that the documents submitted herein be considered and made of record in this application.

Respectfully submitted,

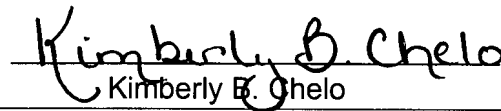


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